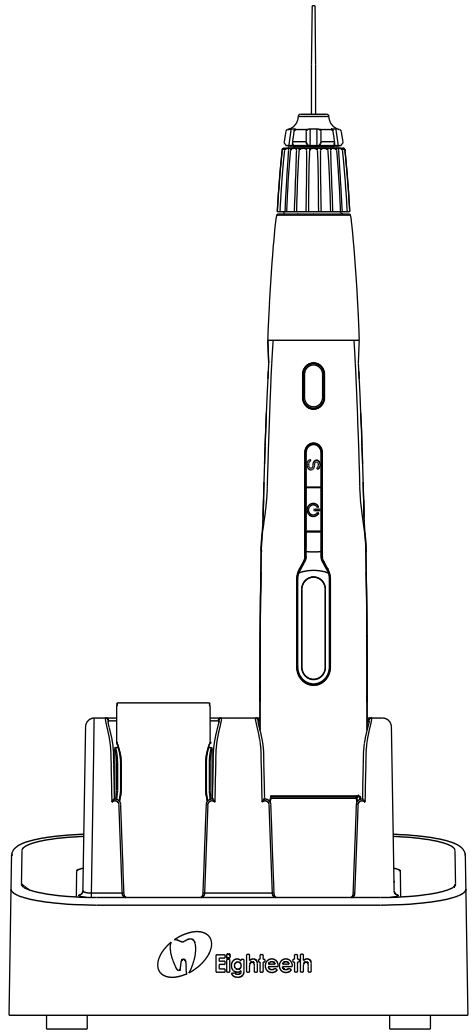
Eighteeth



Space-Fill

USER MANUAL

P/N: IFU-6335206

Version: 01

Issued: 2024.07.15

Size: 85mm×119mm

Content

1.Scope of Space-Fill

1.1 Parts Identification

① Gutta Percha Injecting Needle

② Thermal Protector Cap

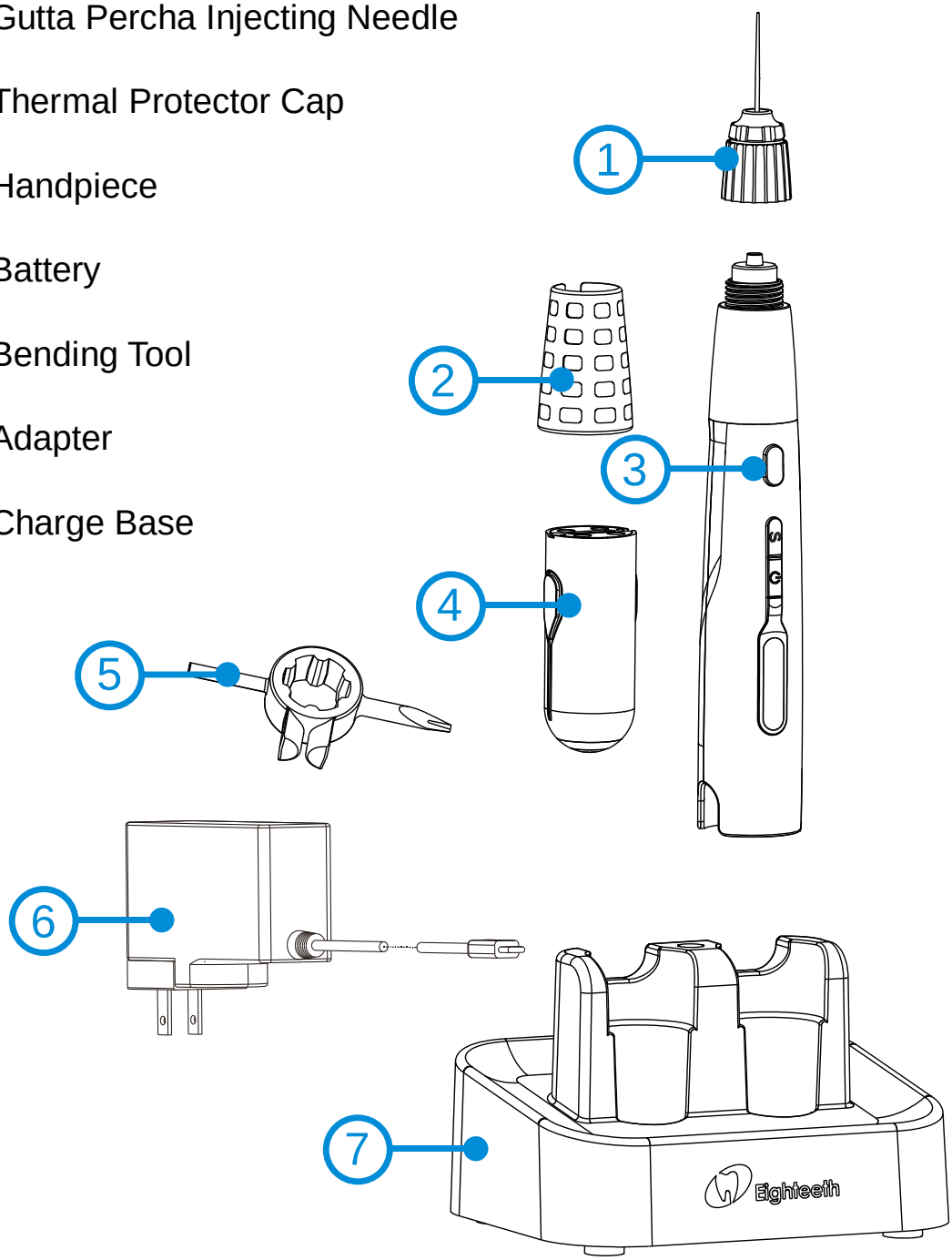
③ Handpiece

④ Battery

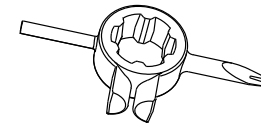
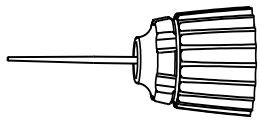
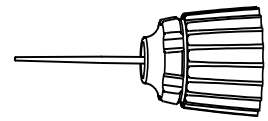
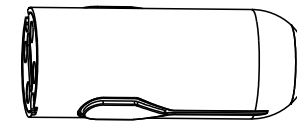
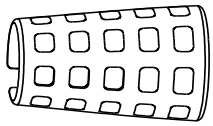
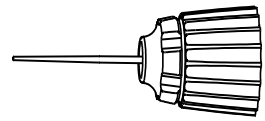
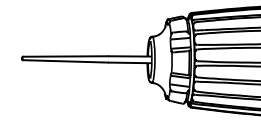
⑤ Bending Tool

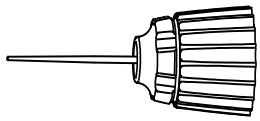
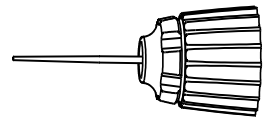
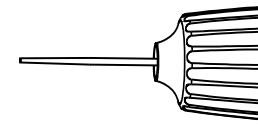
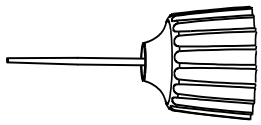
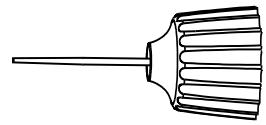
⑥ Adapter

⑦ Charge Base

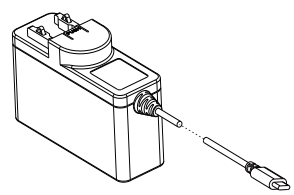
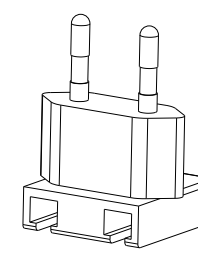


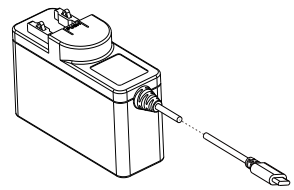
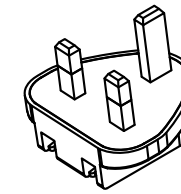
1.2 Components

Handpiece (1 pc) 	Charge Base (1 pc) 	Bending Tool (1 pc) 
Gutta Percha Injecting Needle (1 pc) Size: 25Ga 	Gutta Percha Injecting Needle (1 pc) Size: 23Ga 	Battery (2 pcs) 
Thermal Protector Cap 	Gutta Percha Injecting Needle (1 pc) (Optional accessories) Size: 27Ga 	Gutta Percha Injecting Needle (1 pc) (Optional accessories) Size: 25Ga-L 
Gutta Percha Injecting Needle (1 pc) (Optional accessories) Size: 23Ga-L	Gutta Percha Injecting Needle (1 pc) (Optional accessories) Size: 27Ga-L	Gutta Percha Injecting Needle (1 pc) (Optional accessories) Size: 23Ga-D

		
Gutta Percha Injecting Needle (1 pc) (Optional accessories) Size: 25Ga-D 	Gutta Percha Injecting Needle (1 pc) (Optional accessories) Size: 27Ga-D 	

For different regions, there are several different adapter options to be selected as follows.

Standard	**Adapter**	**Power plug**
European standard	**Adapter (1 pc)** 	**European standard power plug (1 pc)** 

<table>
<tr><td rowspan="3">Multi-standard</td><td rowspan="3">Adapter (1 pc)
  </td><td>British standard power plug (1 pc)
  </td></tr>
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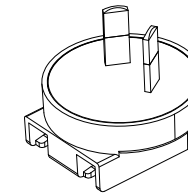
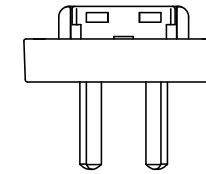
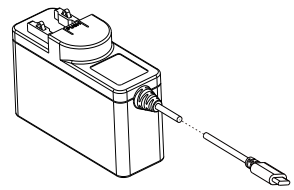
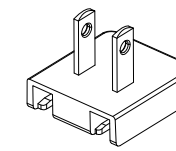
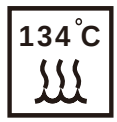
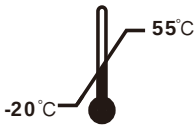
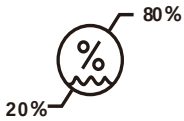
  </td></tr>
<tr><td>Argentina standard power plug (1 pc)
  </td></tr>
<tr><td>American standard</td><td>Adapter (1 pc)
  </td><td>American standard power plug (1 pc)
  </td></tr>
</table>

2. Symbols used

	General warning sign
	Caution
	Serial number
	Catalogue number
	Batch code
	Medical device
	Manufacturer
	Country of manufacture
	Class II equipment
	Type B applied part
	Do not reuse
	Caution, hot surface
	Washer-disinfector for thermal disinfection

2 Symbols used

	Direct current
	Alternating current
	Keep dry
	Dispose of in accordance with the WEEE directive
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Consult instructions for use
	Manufacturer‘s Logo

3. Before Use

3.1 Scope of application

Space-Fill is intended for heating and extruding Gutta-percha into cleaned and shaped canals during root canal treatment.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.

3.2 Contraindications

This device must not be used in cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.)

Do not use on patients with a known sensitivity to natural rubber latex or silver.

Safety and effectiveness have not been established in pregnant women and children.

Before use, please read the following instructions carefully:

- You should carefully read and understand all the contents of the manual before operating.
- All warnings and instructions on the equipment should be followed during operation.
- The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- Do not use this device in environments with free oxygen, anesthetic gases, or flammable materials. This device must be operated, used, and stored in a safe environment.
- This device may cause radio interference or disrupt the operation of nearby devices. At this point, the orientation or placement should be readjusted and shielding should be set up in close proximity to the equipment to minimize its interference impact. The electromagnetic radiation emitted by this device complies with relevant regulatory requirements.

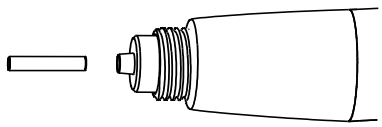
3 Before Use

- This device requires special precautions regarding electromagnetic compatibility (EMC). Do not use this device near strong fluorescent lamps, wireless transmitters, remote control devices, handheld and mobile high-frequency communication devices.
- Do not charge, use, or store this device at high temperatures. Please pay attention to the usage and storage conditions.
- Gloves and rubber barriers must be used during treatment procedures.
- Please do not disassemble or repair this device without authorization, otherwise it will automatically lose its warranty qualification.
- If any abnormal phenomena occur during the treatment process, please immediately shut down the device and contact the local dealer for handling.
- Under normal use, the operator is not allowed to touch the patient while touching the two charging terminals of the charging base.
- Clinical studies have shown that filling temperatures of 160 ℃, 180 ℃, and 200 ℃ do not cause thermal damage to periodontal tissues, but the filling temperature of 200 ℃ should be set with caution.
- Prohibit the use of non-original accessories.
- The maximum temperature of the applicable components may reach 60 ℃, please do not load and use the equipment for a long time. Otherwise, the temperature of the equipment will increase, which may cause minor burns to the operator or patient.
- It is recommended to have the equipment and its accessories inspected at the dealer's location once a year.
- It is prohibited to modify the equipment without authorization from the manufacturer.

4. Installing the Space-Fill

4.1 Installing the Gutta-percha

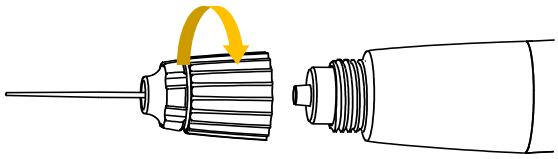
Push the Gutta-percha into the handpiece.



● This product is not included the Gutta-percha. Please use the Gutta-percha that is recommended by Sifary. Refer to the Technical data of this manual for the recommended Gutta-percha size.

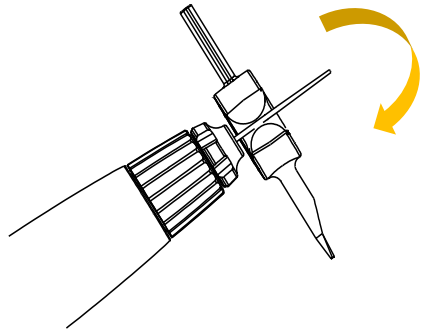
4.2 Installing the Gutta Percha Injecting Needle

During installation, tighten the gutta percha injecting needle along the thread of the front section of the handpiece.

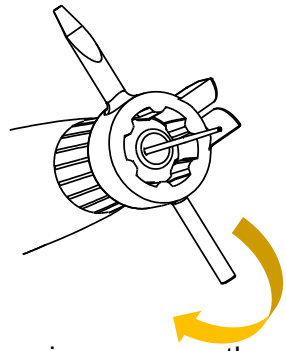


The needle tube cannot be rotated or pulled forcefully.

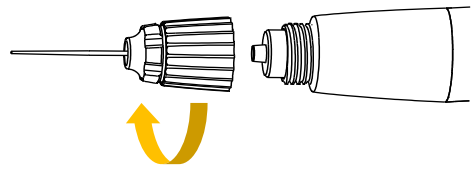
Please use the bending tool when pre bending the silver needle, and do not directly pre bend it by hand.



When the gutta percha injecting needle needs to rotate, please use the bending tool to cover the slot on the needle seat and slowly turn it to the desired position.

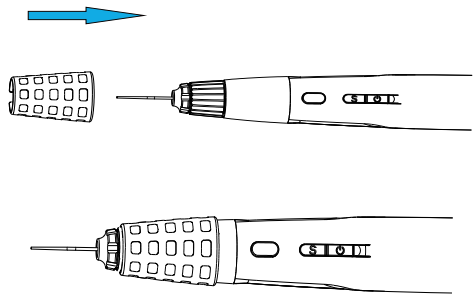


When removing, unscrew the gutta percha injecting needle in the opposite direction from the host handpiece.

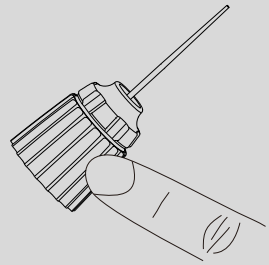


4.3 Installing the Thermal Protector Cap

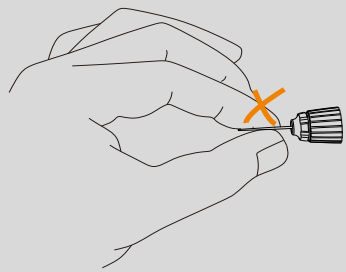
Install the thermal protector cap into the handpiece in the direction of the arrow.



- When unscrewing the gutta percha injecting needle, as shown in the figure below, lightly touch the plastic shell of the gutta percha injecting needle with your fingers to ensure that it is not hot to the touch before operation. If the temperature is too high, please wait for 3-5 minutes before operating.
- If the Gutta-percha has not been used up the Gutta-percha should be pushed out before unscrewing the gutta percha injecting needle. Otherwise, the gutta-percha cannot be filled, and there is a risk of high-temperature Gutta-percha overflow causing burns and Gutta-percha adhesion to the sealing surface.
- After the operation, please promptly remove the gutta percha injecting needle to avoid accidental damage.
- Do not start heating without the gutta percha injecting needle installed, as this may cause Gutta-percha overflow, posing a risk of burns or adhesion to the sealing surface.

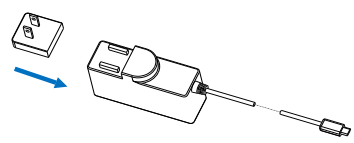


- Even if the gutta percha injecting needle has cooled down, it is strongly recommended that users do not touch the metal parts on the gutta percha injecting needle, as there is a risk of burns or damage to the gutta percha injecting needle.



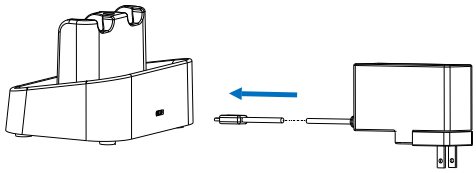
4.4 Installing the Adapter

Plug the head into the base if they are separated in the package.

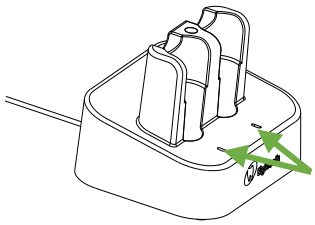


4.5 Connecting the charge base

Plug the USB of adapter into the charge base, and plug the other end into a power outlet.



The Power LED on charge base will light up in blue.

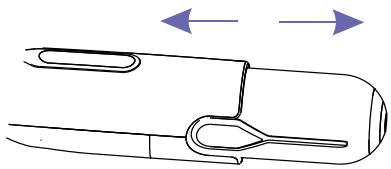


Power and charging status indicator lights

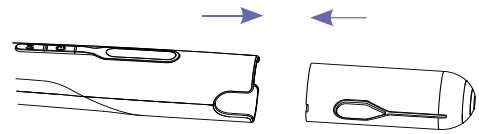
- Only the original adapter can be used.
- Don't position the device where it is difficult to operate the disconnection device.

4.6 Replacing the battery

Pull out the battery outward.



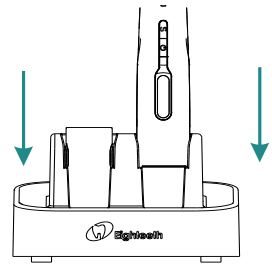
Align the raised part of the fully charged battery with the groove of the handpiece and insert it until you hear the click indicating that the battery is securely in place.



- When the machine is not used for a long time, the battery should be removed.

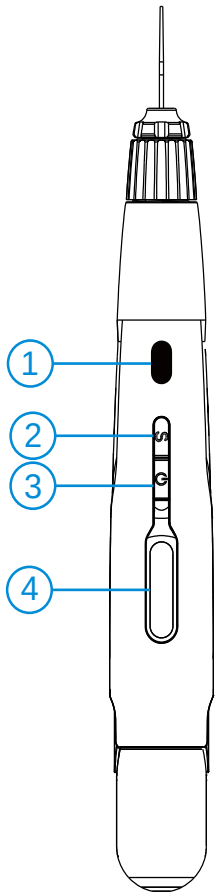
4.7 Charging handpiece and battery

Place the handpiece (with the battery installed) or the battery into the charge base. The charging indicator light on the base will turn green to indicate a proper connection. A flashing green light indicates that charging is in progress. A steady green light indicates that the battery is fully charged.



- If the green light does not turn on when the handpiece (with the battery installed) or the battery is placed on the base, it means the handpiece (with the battery installed) or the battery is not properly positioned. Remove the handpiece (with the battery installed) or the battery and reposition it until the green light turns on.

5. Use Interface



① Main switch

② Set switch

③ Power switch

④ Display Screen

Turn Power On

Long press .

Change Memory Mode

Shore press to change temperature memory mode from T1 to T5.

Memory Parameter Setting

During standby state, holding down press more than 2 seconds to enter memory parameter setting. Parameter T1 to T5 can be set independently. Press till target setting, press to adjust, then press to confirm.

Heating

During standby state, short press and the indicator light flashes. When the preset temperature is reached, the indicator light will remain on.

Stop heating

During heating or in insulation state, short press .

Push out Gutta-percha

When the heating is completed, the indicator light will be on.

When the " Inject Control " mode is off, holding down press to push out the Gutta-percha, stop pressing to stop pushing the Gutta-percha.

When the " Inject Control " mode is set to gears 1-5, long press (for more than 1.5 seconds) to push

	out the Gutta-percha, stop pressing to stop pushing the Gutta-percha. Short press (less than 1.5 seconds) , the machine will automatically push the Gutta-percha to the set value and then stop. **Turn Power Off** During standby state, long press more than 2 seconds. **Advanced Setting** During power off state, holding down press , then press to enter advanced setting. Press till target setting, press to adjust, then press to confirm.

6. Setting

6.1 Memory Parameter Setting

	Space-Fill has 5 memory modes, from T1-T5. In standby mode, press Ⓢ to switch, and the memory mode code will change accordingly.
	In T1-T5 memory mode, holding down press Ⓢ for 2 seconds to enter the "Temperature " setting interface and change the temperature in this memory mode. Press ⬬ till target temperature, the temperature can be set 100℃, 120℃, 140℃, 150℃, 160℃, 180℃, 200℃. Press Ⓢ to confirm and enter next interface.
	Enter the "Push Speed" interface to change the Gutta-percha pushing speed in this memory mode. Press ⬬ till target speed, the speed can be set Low, Mid, High. Press Ⓢ to confirm and enter next interface.
	Enter the "Inject Control" interface to change the injection control function in memory mode. Press ⬬ till target parameter, and the "Inject Control" can be set to: OFF, 1, 2, 3, 4, or 5. Select the "OFF", and the injection control function will be turned off. Select the 1 to 5, and the time for injecting Gutta-percha will increase sequentially. Press Ⓢ to confirm and enter next interface.
	Enter the "Change GP" interface to choose whether to replace the Gutta-percha. Press ⬬ to select "Yes" or "No".

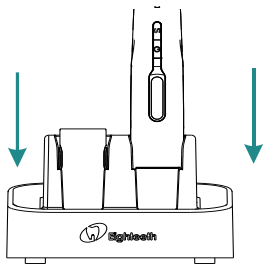
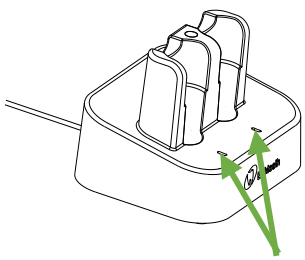
	Press Ⓢ to confirm and return to standby interface.

6.2 Advanced Setting

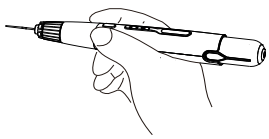
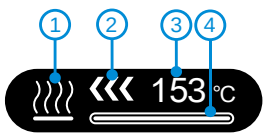
	During power off state, holding down press ▬ , then press ⏻ to enter advanced setting, the “Auto Power Off” will appear on the display screen. Press ▬ to adjust, the auto power off time can be set to 5, 10 and 15 minutes. Press Ⓢ to confirm and enter next interface.
	Enter the "Beep Volume" interface to change the volume of the prompt sound. Press ▬ to adjust. The “Beep Volume” can be set to 0, 1 and 2. Press Ⓢ to confirm and enter next interface.
	Enter the "Restore Settings" interface to change the reset settings. Press ▬ to adjust. Press Ⓢ to confirm and enter next interface. ⚠ ● If choose “YES”, all the setting parameters will be covered by factory settings.
	Enter the " Save " interface to confirm whether to save the settings. Press ▬ to adjust, press Ⓢ to save and power off.

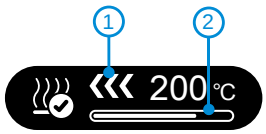
7. Operation

7.1 Charge

	Display the present remaining amount of the battery. This icon indicates that the remaining battery is less than 15%, please charge in time. ● If the battery power if less than 15%, the device must be recharged within 30 days, otherwise the battery will be damaged.
	Place the handpiece (with the battery installed) or the battery into the charge base. Both slots on the base have the same function and can charge the device.
 Power and charging status indicator lights	During charging, the green charging indicator light on the base will flash. When the battery is fully charged or nearly fully charged, the green indicator light will stay on. It takes about 1 hour to fully charge the battery. If the remaining battery level or the condition of the battery (such as aging) varies, the charging time may differ. According to the usage of the device, the battery can be recharged 300 times, and then the battery level will significantly decrease. ● Do not use non original batteries. If the wrong battery is used, electronic components will be damaged.

7.2 Heating and Using

	After selecting a memory mode, press ⬬ to heat the gutta percha injecting needle. ⚠ ● Push out insufficiently warmed Gutta-percha about 3mm before each use.
	During the heating process, the LED indicator light flashes. After heating to the set temperature (about 5-20 seconds), the LED indicator light stays on and enters the insulation state. ⚠ ● If the machine enters the insulation state after heating is completed and the handpiece is not operated for a long time (2 minutes), the machine will exit the insulation state (the LED indicator light will turn off) and return to the initial interface. ● After heating, the gutta percha injecting needle should not stay in the root canal for more than 5 seconds to avoid burning the patient. ● Do not touch the gutta percha injecting needle during the heating process to prevent burns.
	① Heating indication. When the set temperature is reached, heating process will switch off and “ ”will display on screen. ② Direction of pushing ③ Real time heating temperature ④ Gutta-percha residual



After heating is completed, in T1-T5 modes, with the " Inject Control " mode off, long press [redacted] to start pushing the Gutta-percha. Stop pressing and stop pushing the Gutta-percha. At the same, ① the light of direction flashes, indicating the push rod is moving forward to push out the Gutta-percha. ② Display the real-time remaining amount of Gutta-percha.

After heating is completed, in T1-T5 modes, with the " Inject Control " mode set to gears 1-5, press and hold (for more than 1.5 seconds) [redacted] to continuously push out the Gutta-percha. Stop pressing and stop pushing the Gutta-percha. Short press [redacted] (not exceeding 1.5 seconds), the Gutta-percha will be automatically pushed out until the set value is reached, and then it will stop. ① The light of direction flashes, indicating the push rod is moving forward to push out the Gutta-percha. ② Display the real-time remaining amount of Gutta-percha.

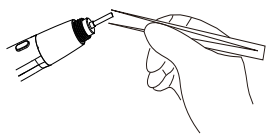
Press ⏻ to exit and return to standby interface.

- If there is a little residual Gutta-percha in handpiece or gutta percha injecting needle. The gutta percha injecting needle will be used again after the replacement of Gutta-percha, tighten the gutta percha injecting needle again to prevent leak Gutta-percha after heating.
- If there is too much residual Gutta-percha in handpiece or gutta percha injecting needle, please refer to daily cleaning process.
- Please use good mobility Gutta-percha, otherwise the Gutta-percha will leak. If leaking please refer to daily cleaning process.
- After use, promptly place the handpiece back on the charge base.
- Adjust the heating temperature of the device according to the recommended usage temperature of the Gutta-percha.
- During use, the temperature at the needle tip is close to the set temperature of the handpiece. Do not touch it to avoid burns.

7.3 Changing Gutta-percha

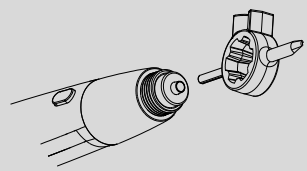
	During standby state, holding down press Ⓢ to enter memory parameter setting. Press Ⓢ till “Change GP”. Press till “Yes” and press Ⓢ to confirm.
	Firstly, the handpiece will heat to about 150℃ to melt the residual Gutta-percha.
	Secondly, the pushrod pushes forward until the Gutta-percha is exhausted. The direction of push rod movement displays on the screen.
	Then, the direction and position of push rod display on the screen. The push rod needs returning to original position. This operation takes about 50 seconds.
	Finally, when the pushrod is back to original position, “Please insert GP” will display on the screen. Press any key to exit and return to standby interface.

- During this state, press ⏻ can stop and return to standby interface.



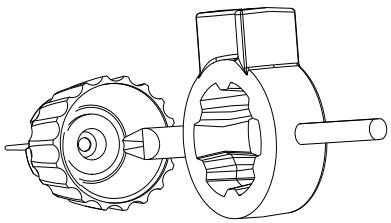
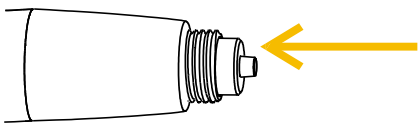
After pushing the Gutta-percha into handpiece with medical forceps, screw down the gutta percha injecting needle.

- If there is some Gutta-percha in the handpiece, it is inconvenient to install the Gutta-percha. Push the residue to the bottom of cavity with the pin on bending tool.



8. Maintenance

8.1 Daily cleaning

Daily cleaning	
	Use the bending tool as shown in the diagram to clean the residual Gutta-percha inside the gutta percha injecting needle.
	Use a tissue or alcohol to wipe off the Gutta-percha that has spilled from the mouth of the cavity. ⚠ ● Do not use sharp and hard tools to scrape the metal cone surface of the gutta percha injecting needle and the handpiece, otherwise it may scratch the cone surface and affect the sealing of the Gutta-percha.

8.2 Cleaning, Disinfection and Sterilization

8.2.1 Foreword

For hygiene and sanitary safety purpose, the components (Gutta Percha Injecting Needle, Bending Tool and Thermal Protector Cap) must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent uses. Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

Reprocessing procedures have only limited implications to this dental device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. The Bending Tool and Thermal Protector Cap are verified to

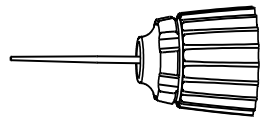
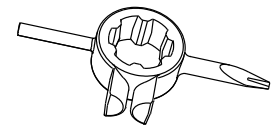
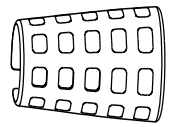
be able to withstand 250 times reprocessing cycles. The gutta percha injecting needle can only be reprocessed once. The device should no longer be reused in case of signs of material degradation.

In case of damage, the device should be reprocessed before sending back to the manufacturer for repair.

8.2.2 General recommendations

- The user is responsible for the sterility of the product before the first use and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- Clean the products within two hours after each use.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- The water quality must meet the requirements of EN 13060.
- Thoroughly clean and wash the components before autoclaving.
- Do not use bleach or chloride disinfectant materials.

8.2.3 Autoclavable accessories

Autoclavable accessories			
Gutta Percha Injecting Needle		Bending Tool	
Thermal Protector Cap			

- Only the above components can undergo high-temperature steam sterilization and can withstand up to 250 cycles of high-temperature steam sterilization (the gutta percha

injecting needle can only undergo one cycle of high-temperature steam sterilization). ● Before first use and after each use, the bending tool and thermal protector cap components must be sterilized with high-temperature steam. ● The gutta percha injecting needle should be sterilized before use and disposed of as medical waste after use.	
Reprocessing instructions	
Preparation at the point of use	Remove gross contaminations from the components with a cloth, which dipped in cold water (0-40°C) immediately after use. Don't use a fixating detergent or hot water (40-100°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.  ● Do not wipe the motor with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agents to the components.
Transportation	Safe storage and transportation to the reprocessing area to avoid any damage and contaminate on to the environment.
Preparation for Decontamination	The devices must be reprocessed in a disassembled state.  ● Observe suitable personal protective measures.
Pre-Cleaning	Manually pre clean until the appearance of the components is clean. Immerse the above components in a cleaning solution and rinse with a cold water spray gun for at least 10 seconds. Clean the surface with a soft bristled brush.
Cleaning	**Automated cleaning:**

	Carefully put the components into the washer-disinfector on a tray and set the parameters as follows, then start the program: 4 min pre-washing with cold water (0-40°C); Emptying 5 min washing with a mild alkaline cleaner (pH value between 7.5 and 8.5) at 55±2°C; Emptying 3 min neutralising with warm water (40-60°C); Emptying 5 min intermediate rinsing with warm water (40-60°C); Emptying Note: The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert) and Rapid-A520 Washer-disinfector from Shandong Xinhua Medical Device Co., Ltd.  ● Use only approved wash-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. ● Please strictly follow the concentration of cleaning agent provided by the manufacturer for cleaning.
Disinfection	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements with regard to A0 value (refer to EN ISO 15883). A disinfection cycle of 5 min disinfection at 93±2°C has been validated for the device to achieve an A0 value of 3000. After cleaning, the parts should be automated disinfected or sterilized immediately. A manual disinfection is not recommended.
Drying	**Automated Drying:** Drying the devices according to drying program of

	washer/disinfector by setting parameter 120 °C, 15 min. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of devices by using sterile compressed air.
Functional Testing, Maintenance	Visual inspect the cleanliness of the components and reassemble them. Conduct functional testing according to instructions of use. If necessary, perform reprocessing process again until the components are visibly clean. Before packaging and autoclaving, make sure that the components have been maintained according to the manufacturer's instruction.
Packaging	The devices that require sterilization can be packaged together in one pounch, but it is necessary to ensure that the packaging pounch is large enough and will not be damaged due to excessive volume.  ● Check the validity period of pouch given by the manufacturer to determine the shelf life. ● Use pouches which resist to a temperature up to 141℃ and in accordance with EN ISO 11607.
Sterilization	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: 5 min at 134±2°C Drying time: at least 8min  ● Use only approved autoclave devices according to EN 13060 or EN 285.

	● Use a validated sterilization procedure according to EN ISO 17665. ● Respect the maintenance procedure of the autoclave device given by the manufacturer. ● Use only this recommended sterilization procedure. ● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycle parameters). ● Wait for cooling before touching.
Storage	Store the sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and User Manual.  ● Sterility cannot be guaranteed if packaging is open, damaged or wet.

● The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

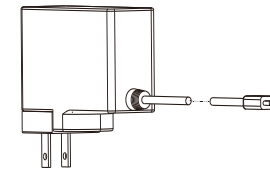
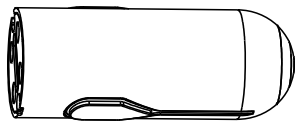
● Please comply with relevant regulations for cleaning, disinfection, and sterilization.

● Please be careful during maintenance to avoid cross infection.

● The next patient should replace the cleaned, disinfected, and sterilized the gutta percha injecting needle, bending tool and thermal protector cap.

- The gutta percha injecting needle are easily damaged by external forces, so be careful when maintaining them.
- Be careful when cleaning, disinfecting, and sterilizing, and wear disposable sterile gloves to avoid cross infection.

8.2.4 Disinfection components

Disinfection components		
Handpiece 	Charge Base 	Adapter 
Battery 		

Cleaning	Wipe the outer surface of the machine with a soft cloth soaked in Ethanol (70-80 vol% Ethanol) more than 5 times for 2 min each time, until there are no visible stains.
Disinfection	Wipe the outer surface of the machine with a soft cloth soaked in Ethanol (70-80 vol% Ethanol) more than 5 times for 2 min each time.
Drying	Use a dry lint free sterile cloth to wipe off the residual water on the devices until no water stains remain.
Inspection and maintenance	Visual inspect the cleanliness of the components and reassemble them. Conduct functional testing according to instructions of use. If necessary, perform reprocessing process again until the

	components are visibly clean.
Storage	Store the sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and User Manual.

- Do not use disinfectants other than ethanol for disinfection (Ethanol 70 to 80 vol%).
- Do not use excessive ethanol to prevent ethanol from seeping into the parts and damaging the internal parts.
- The above components must be disinfected before first use and after each use.
- When used by patients, the equipment should not be maintained or serviced.

9. Troubleshooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

Problem	Cause	Solution	Ref.chap
The power is not turned on.	The battery level is too low.	Charging the handpiece (with battery installed) or battery	7.1
	Press the power switch too short time.	Long press the power switch.	5
The power LED on charge base does not light.	Using a wrong adapter.	Use the original adapter.	4.4
	The adapter is not connected.	Check the connection.	4.4
	The plug of the adapter is not inserted into the outlet.	Check the connection.	/
	There is no electricity in the outlet.	Check the connection.	/
The charging indicator light on the charge base does not turn green.	The handpiece (with battery installed) or the battery is not properly seated.	Please remove the main unit (with the battery installed) or the battery and then reposition it.	4.7
	Charge pin of charge base is unable to rebound.	Remove debris which between move part and base of the	/

		charge pin.	
	Contactors are dirty.	Cleaning the surface of contactors.	/
	The charge base is broken.	Contact the dealer to repair the charge base	/
Handpiece screen does not appear.	The handpiece is broken.	Check if there is a sound of beep, and contact your distributor.	/
No sound.	Beep volume is set to 0.	Set beep volume to 1 or 2.	6.2
	During the heating process, the temperature sensor or heating circuit is abnormal.	Please contact the dealer for repairs.	/

10. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd.
Model	Space-Fill
Gutta-percha size	Diameter：2.5mm-2.8mm Length：14mm-16mm Applicable temperature: 100℃-200℃
Battery	Lithium ion battery: 3.7V, 1100mAh
Adapter input	100-240V～
Adapter output	6V
Adapter output	3A
Input	0.5A
Frequency	50/60Hz
Temperature	100℃~200℃, ±10%
Type of protection against electrical shock	Class Ⅱ, internal power supply equipment
Waterproof protection strength	IPX0
AP/APG type equipment	Non AP/APG equipment
Anti defibrillation application part	None
Application part	B (Gutta Percha Injecting Needle)
Operation mode	Continuous operation
Operating conditions	Ambient temperature: 5℃~40℃

	Relative humidity: ≤80% Working altitude: ＜3000m above sea level
Transport and storage conditions	Ambient temperature:-20℃~ +55℃ Relative humidity:20% ~ 80% Atmospheric pressure:70kPa~ 106 kPa

11. EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The **Space-Fill** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Space-Fill** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Professional healthcare facility environment and Home healthcare environment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	Professional healthcare facility environment.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliances	

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration – electromagnetic immunity

11 EMC Tables

The **Space-Fill** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Space-Fill** should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Surges Line to line: ±0.5kV, ±1kV Surges Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°,	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°,	Mains power quality should be that of a typical commercial or hospital environment.

Voltage interruptions IEC 61000-4-11	180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT; 250/300 cycle	225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT; 250/300 cycle	If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery
Rated Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			
Guidance and manufacturer's declaration – electromagnetic immunity			
The **Space-Fill** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Space-Fill** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands and amateur radio bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be usedno closer to any part of the **Space-Fill**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF EM fields IEC 61000-4-3 .	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz	3V/m	**Recommended minimum separation distances** See the RF wireless communication equipment table in "Recommended minimum separation distances"
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	

Recommended minimum separation distances

11 EMC Tables

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **Space-Fill** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the **Space-Fill** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820,	Pulse modulation 18Hz	2	0.3	28
870						
930						

		CDMA 850, LTE Band 5				
1720	**170**	**GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS**	**Pulse modulation 217Hz**	**2**	**0.3**	**28**
1845						
1970	**199**					
2450	**240**	**Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7**	**Pulse modulation 217Hz**	**2**	**0.3**	**28**
	257					
5240	**510**	**WLAN 802.11 a/n**	**Pulse modulation 217Hz**	**0.2**	**0.3**	**9**
5500						
5785	**580**					

Guidance and manufacturer's declaration – electromagnetic immunity			
The Space-Fill is intended for use in the electromagnetic environment specified below. The customer or the user of the Space-Fill should assure that it is used in such an environment.			
Proximity magnetic fields	**IEC 61000-4-39 test level**	**Compliance level**	**Electromagnetic environment – guidance**

Proximity magnetic fields	134.2kHz Pulse modulation 2.1 kHz	65A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	13.56MHz Pulse modulation 50 kHz	7.5A/m	

1. Use of accessories and cables other than those specified or provided by the manufacturer of Space-Fill could result in increased electromagnetic emissions or decreased electromagnetic immunity of Space-Fill and result in improper operation.

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter Cable	2.0	No	/

2. Use of Space-Fill adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, Space-Fill and the other equipment should be observed to verify that they are operating normally.

3. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Space-Fill, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4. If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

12. Warranty

1. Space-Fill is warranted against manufacturing errors and defects in materials, and the warranty period is 12 months starting from the day of delivery to the customer.

2. Space-Fill should be repaired by the equipment technology department of Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partners authorized by Changzhou Sifary Medical Technology Co., Ltd. Do not provide circuit diagram, bill of material, legends, calibration rules, and other maintenance materials to other organizations.

3. Should the quality assurance complaint be reasonable, Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partner authorized by Changzhou Sifary Medical Technology Co., Ltd shall provide repairing service as soon as possible.

4. Should the damage be proved to be caused by the user's negligence in daily maintenance, warranty is then voided.

5. Changzhou Sifary Medical Technology Co., Ltd reserves the right to analyze and determine the cause of any problems.

13. Statement

Service Life

The service life of Space-Fill series products is 10 years.

Maintenance

MANUFACTURE will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Those parts of the equipment that shall not be serviced or maintained while in use with a PATIENT:

- Handpiece
- Gutta Percha Injecting Needle
- Bending Tool
- Thermal Protector Cap

Disposal

Comply with your national regulations, guidelines and requirements for the disposal of waste electrical equipment and medical devices.

Make sure the device is not mixed with other types of waste when it is being disposed of.

Rights

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.

13 Statement

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